IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Ethicon Wave 8 cases listed in Exhibit A to Plaintiffs' original motion*	

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS OF DEFENSE EXPERT AHMET BEDESTANI, M.D.

The Plaintiffs in this MDL respectfully submit this Reply Brief in further support of an order precluding defense expert Ahmet Bedestani, M.D., from testifying in any of the Ethicon Wave 8 cases. This Reply will briefly address each of Ethicon's response arguments. This Court should preclude Dr. Bedestani from opining about the safety and efficacy of the Prosima device, which was used to treat pelvic organ prolapse ("POP"); about whether the warnings on the device were sufficient; about whether the device was defectively designed; and about whether the device was the "state of the art" while it was briefly on the market.

I. Defendants have not met their burden to show that Dr. Bedestani has the necessary education or experience to testify about whether the Prosima device was safe and effective, nor have they met their burden to show that his methodology was reliable.

Dr. Bedestani does not have the necessary expertise to opine that the Prosima was a safe and effective device when it was on the market for approximately three years. Notably, Dr. Bedestani could not get into medical school in the United States and instead attended school on

the Caribbean island of Dominica. (*See* Memo in Support, Dkt. No. 6888, at p. 5). While these facts do not by themselves disqualify Dr. Bedestani as an expert, they go directly to one of the factors mentioned in Rule 702: education. The proponent of the witness has the burden of establishing that the expert is qualified. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 1999 (4th Cir. 2001). Without more information about Dr. Bedestani's medical school—which has not been provided—education cannot serve as a basis for his expertise.

Another potential basis for expertise is experience, but again Defendants have not met their burden to establish Dr. Bedestani's credentials. Dr. Bedestani has never used the Prosima while practicing as a physician, and he does not use any mesh in his practice today. (*See* Memo in Support, Dkt. No. 6888, at p. 5). Defendants focus largely on two factors in trying to defend Dr. Bedestani: the number of pelvic floor surgeries he has performed, and the number of hours that he supposedly spent studying the scientific literature. Dr. Bedestani asserts that he has performed more than 1,000 surgeries to correct pelvic organ prolapse, (*see* Def. Resp. Br., Dkt. No. 6995, at p. 5), but his report says nothing about how many of those surgeries involved mesh. The report also states that over the past six years, Dr. Bedestani's practice has focused on robotic-assisted approaches to the surgical management of POP. (Bedestani Report, Ex. B to Dkt. No. 6884, at p. 2). The mere fact that he performed surgeries does not make him an expert on a device that was not involved in many of those surgeries. Defendants criticize Plaintiffs for not exploring at Dr. Bedestani's deposition why he does not use mesh. (Def. Resp. Br., Dkt. No. 6995, at p. 5). But again, it is the Defendants' burden to establish the qualification of this witness. If there was some reason other than, "this physician who plans to testify that mesh is safe and effective does not believe that enough to use it himself," then Defendants should have included that reasoning in their response.

Regarding Dr. Bedestani's methodology in reaching his opinions, Defendants cannot contest that he billed only 64.4 hours for his work on forming his opinions, including the authorship of a 28-page, single-spaced, expert report with 118 footnotes. (*See* Bedestani General Prosima Report, Ex. B to Dkt. No. 6884). Dr. Bedestani did testify that he used his retention as "an exercise to satisfy intellectual curiosity," but he did not identify any work that he did "off the books," other than spending an estimated seven hours reviewing the basics of organic chemistry. (*See* Bedestani Dep., Ex. A to Dkt. No. 6884, at 13:2-10). To the extent that Dr. Bedestani needed to do extra work to familiarize himself with basic concepts, that fact only underscores why his status as an "expert" in this litigation is highly questionable.

Because Ethicon has not met its burden to establish that Dr. Bedestani is qualified to opine as to the safety and efficacy of Prosima, or to establish that his methodology was reliable, this Court should exclude those opinions.

II. Dr. Bedestani has not provided any information that shows he is qualified to opine about the sufficiency of Ethicon's warnings, or to show that he can reliably gauge the information that other physicians would have needed.

The Court should have little trouble concluding that Dr. Bedestani is unqualified to opine about product warnings. Ethicon has provided absolutely no information about Dr. Bedestani's experience or knowledge to meet its burden on that point.

Ethicon argues that "[t]he legal principle that controls here is that a medical device manufacturer's duty to warn of adverse events does not include a duty to warn of risks commonly known to surgeons who use the device." (Def. Resp. Br., Dkt. No. 6995, at p. 8). Even accepting that "legal principle" as accurate, for the sake of argument, the physician still has to demonstrate the necessary expertise to make that evaluation, under Rule 702. Defendants

have provided no information as to how Dr. Bedestani came to the conclusion that Ethicon provided all of the warnings that were necessary on the Prosima.

This Court has previously excluded an expert who actually participated in drafting the warnings for the Prosima—when Dr. Slack was attempting to offer warnings opinions about another product. *Sanchez v. Boston Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *32 (S.D.W. Va. Sept. 29, 2014). Ethicon cites *Winebarger v. Boston Scientific Corp*., No. 2:13-cv-28892, 2015 WL 1887222, at *15 (S.D. W. Va. Apr. 24, 2015), in support of its argument that Dr. Bedestani should be allowed to offer his warnings opinions in this case. However, in *Winebarger*, the Court simply ruled that Dr. Shull was qualified to testify as the risks he perceives to patients, and also offer the opinion that the Uphold DFU did not adequately convey those risks. *Id*. At no time did Dr. Shull attempt to get into the minds of other physicians. He offered no opinions as to whether all physicians knew about the Uphold's risks, which is precisely what Ethicon would have Dr. Bedestani do here.

Dr. Bedestani has provided no information about his methodology in concluding that physicians would have known about the risks presented by Prosima. Nor does he have the additional expertise that this Court has consistently required when allowing physicians to opine as to whether particular warnings were adequate. *See, e.g., In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding Dr. Shull from testifying about the adequacy of Bard's warnings). At most, Dr. Bedestani should be permitted to describe the risks presented by Prosima and indicate whether those risks were noted in the warnings, as Dr. Shull was permitted to do. However, there is no reliable foundation for Dr. Bedestani to opine as to the adequacy of the warnings or as to whether physicians generally were apprised of the risks associated with Prosima.

III. Dr. Bedestani's experience in performing pelvic floor surgeries does not qualify him to opine about the design or physical properties of the mesh, as the large majority of his clinical experience does not involve mesh at all.

The Court should also exclude Dr. Bedestani's opinion regarding the design of Prosima. Nothing in the Defendants' response brief counters the Plaintiffs' assertion that Dr. Bedestani lacks the expertise to opine about the design of Prosima. Defendants have also failed to show that his opinions are reliable.

Primarily, the Defendants rely on Dr. Bedestani's experience, again referencing his claim to have done more than 1,000 surgeries in the pelvic floor. (Def. Resp. Br., Dkt. No. 6995, at pp. 11-12). But as discussed above, doing 1,000 surgeries has little meaning when none of them have involved mesh for the last several years. When this Court allowed Dr. Bruce Rosenzweig, a urogynecologist, to give opinions about the properties of the TVT mesh, the Court noted not only that he had performed more than 1,000 pelvic floor surgeries, but also that he had performed more than 200 surgeries dealing specifically with complications due to synthetic mesh. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 707 (S.D. W. Va. 2014). In addition, "Dr. Rosenzweig testified that as early as 2004 or 2005, he determined, as a result of explanting mesh products, that polypropylene degrades in the human body." *Id.* Here, there is no evidence that Dr. Bedestani has performed surgeries dealing with **pelvic mesh** complications, or that he has reached any conclusions about the properties of the mesh based on his clinical experience. The mere fact that he has performed surgeries (mostly without mesh) does not qualify him to opine about the design of Prosima mesh. Presumably, the Court did not intend for its prior orders on other experts to mandate that anyone who has performed pelvic floor surgeries, regardless of how often mesh was involved, would thereby become an expert on the properties and design of pelvic mesh products.

IV. Defendants have failed to show that Dr. Bedestani has any foundation for his opinion that the Prosima device was the "state of the art" while it was briefly on the market.

Finally, there is no support whatsoever for Dr. Bedestani's opinion that the Prosima was the "state of the art" during its brief time on the market. None of the information identified by the Defendants is relevant to that determination.

Defendants cite Dr. Bedestani's testimony in which he compares Prosima to other products and states that only Prosima has a "splint device." (Def. Resp. Br., Dkt. No. 6995, at pp. 12-13). This testimony tells the Court nothing more than that Prosima had a particular feature that other mesh devices did not have. Dr. Bedestani does not explain what this feature is, how it operates, what problem it is supposed to solve, or whether the feature was even successful. The mere fact that a product has some unknown feature that does not exist on other products does not mean that the product is the "state of the art." Dr. Bedestani also states that the Prosima did not "violate" a particular ligament complex. (*Id.* at 13). Again, no context is given, and this remark says nothing about the overall safety and effectiveness of the product.

Defendants offer no additional argument as to how Dr. Bedestani can reliably opine that the Prosima was the "state of the art." Therefore, Dr. Bedestani's claim that the Prosima was a "state of the art" product is wholly unsupported, and it should be excluded.

CONCLUSION

For the foregoing reasons, as well as those stated in the original motion, this Court should exclude the general causation opinions of Dr. Bedestani.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing was filed on October 31, 2018, using the Court's CM/ECF electronic filing system, thereby serving notice of the filing upon counsel for all parties to the case.

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